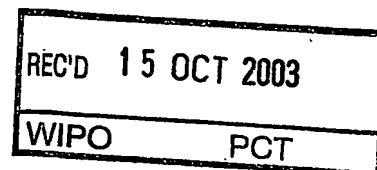


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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 11 September 2002 with an application for Letters Patent number 521364 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 29 September 2003.

A handwritten signature in cursive script, reading "Neville Harris".

Neville Harris
Commissioner of Patents, Trade Marks and Designs



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PROVISIONAL SPECIFICATION

Conduit and Method of Forming

We, FISHER & PAYKEL HEALTHCARE LIMITED a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

BACKGROUND TO THE INVENTION

1. Field of the invention

The present invention relates to components for breathing circuits and in particular to conduits for use in the limbs of breathing circuits. The invention also relates to methods of manufacturing such conduits.

2. Summary of the prior art

In assisted breathing, particularly in medical applications, gases are supplied and returned through conduits. Such conduits are ideally light and flexible to ensure the greatest level of comfort for the patient. In the prior art, thin walled conduits are known which include helical or annular reinforcing ribs which act to give the conduit better resistance to crushing and pinching, while still allowing the conduit to be light and flexible. An example of such a conduit is shown in Figure 1.

It is advantageous to manufacture this type of conduit as a continuous process. In the prior art this is achieved by spiral winding of a thin polymer tape onto a former such that the edges of adjacent layers overlap a small amount. A bead of molten polymer is then applied over top the overlapping edges welding them together and simultaneously forming the helical reinforcing ribs. A disadvantage with this forming technique is the difficulty welding several adjacent layers. This problem is especially severe when multiple layer conduit walls are to be formed. While combining the application of a molten bead with another secondary thermal welding process or applying the polymer to the former as a still molten plastic does go some way to alleviating this difficulty, these solutions add complexity to the tube former and may be difficult to achieve with very thin walls.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a conduit, with particular application to the limbs of a breathing circuit, which will at least go some way towards improving on the above or which will at least provide the public and the medical profession with a useful choice, and/or to provide a method of manufacturing which will at least go some way towards providing the public and manufacturers with a useful choice.

In a first aspect the invention may broadly be said to consist in a continuous conduit forming process comprising applying at least one thin film ribbon, each having "leading" and "trailing" lateral edges, spirally around a former, with the leading edge of each turn of ribbon overlapping the trailing edge of a previous turn of ribbon on the former and the trailing edge of each turn underlapping the leading edge of a succeeding turn, while, in advance of said overlapping of said turns, applying a bead of molten plastic along the exposed trailing edge of the most recently applied turn on said former, such that a said bead is interposed between said trailing edges and said overlapping leading edges.

Preferably said thin film ribbon sufficiently supple, at least laterally, to conform along its overlapping portion to the contour of said bead, so that the overlapping ribbon may meet or substantially meet the underlapping ribbon at the trailing edge of said bead.

In one embodiment the ribbon may be formed from a breathable plastic material. In another embodiment the ribbon may be formed as a laminate where a layer of breathable plastic material is laminated to a reinforcing layer which also allows the passage of water vapour.

In another embodiment the method may include the step of applying one or more heating wires to the exposed trailing edge of the ribbon prior to applying the bead, such that the bead encapsulates the one or more heating wires onto the said trailing edge.

In an alternative embodiment the ribbon may include one or more heater wires embedded within or along its trailing edge. The heater wires may be co-extruded into the ribbon or alternatively the ribbon may include a longitudinal fold with the heater wire disposed within the fold adjacent the fold. In that case advantageously the fold may be non-symmetric such that at its leading edge the ribbon is a single material thickness only.

In a further aspect the invention may broadly be said to consist in a method of forming very thin walled breathing conduits, wherein a sacrificial layer of thin plastic, is first applied around a former, before said very thin walled breathing conduit is formed on said former over top of said sacrificial layer, and said sacrificial layer is removed from inside said very thin walled conduit after cooling.

Preferably said forming method is a continuous forming method.

Preferably said sacrificial layer is a thin ribbon having "leading" and "trailing"

lateral edges, and said ribbon is spirally wound around said former in a continuous fashion, with the leading edge of each turn of ribbon overlapping the trailing edge of a previous turn of ribbon on the former and the trailing edge of each turn underlapping the leading edge of a succeeding turn.

In a further aspect the invention may broadly be said to consist in a conduit formed in accordance with a method according to any one of the preceding paragraphs.

In a still further aspect the invention may broadly be said to consist in a conduit comprising:

at least one thin plastic ribbon having a leading and a trailing lateral edge, said ribbon arranged helically with its face substantially parallel with the helix axis, and, apart from at its ends, the leading edge of each turn of ribbon overlapping the trailing edge of a previous turn, and the trailing edge of each turn of ribbon underlapping the leading edge of a succeeding turn,

a plastic reinforcing bead interposed between each overlapping leading and trailing edge.

In one embodiment the said ribbon may be a breathable plastic material.

In another embodiment said plastic reinforcing bead may include one or more heating wires encapsulated in said bead.

In a still further aspect the invention may broadly be said to consist in apparatus for forming a tube comprising a former for receiving at least one thin plastic ribbon, said former drawing said ribbon around and advancing said ribbon along to procure a helical arrangement of said ribbon, the pitch of said helical arrangement being somewhat less than the width of said ribbon,

means for delivering a ribbon to said former at a first position on said former, and

means for continuously delivering a molten bead to said former at a position less than one turn pitch from the position of delivery of said ribbon said position corresponding to an expected position of the trailing edge of a ribbon delivered by said means for delivering a ribbon.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will

suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross sectional side elevation of a conduit according to an embodiment of the prior art.

Figure 2 is a cross sectional elevation of conduit according to one embodiment of the present invention.

Figure 3 is a plan view of a conduit forming device for forming a reinforced conduit according to the present invention, such as the conduit pictured in Figure 2.

Figure 4 is a cross sectional elevation of a conduit showing a rough inner surface resulting from the tape not following the contour of the molten bead.

Figure 5 is a cross sectional side elevation of a conduit according to a further embodiment of the present invention including outer axial reinforcing threads.

Figure 6 is a plan view of a conduit forming device for forming a reinforced conduit according to the present invention, such as the conduit pictured in Figure 5.

Figure 7 is a cross sectional side elevation of a conduit according to a further embodiment of the present invention including a pair of heater wires within the conduit wall.

Figure 8 is a plan view of a conduit forming device for forming the conduit pictured in Figure 7.

Figure 9a is a cross section of a pre-formed tape including a pair of heater wires according to a further embodiment of the present invention.

Figure 9b is a cross section assembly view of a pair a heater wires being embedded in a polymer tape.

Figure 10 is a cross section view of a conduit including a pair of heater wires formed from the pre-formed tape shown in figure 9b.

DETAILED DESCRIPTION

The present invention relates to breathing conduits in general and in particular to improved methods of forming thin film spiral wound conduits. Consequently the present invention finds application in breathing conduits fabricated from a variety of materials which may include breathable and/or non-breathable materials (breathable materials being capable of transmitting water vapour).

In assisted breathing, particularly in medical applications, gases having high levels of relative humidity are supplied and returned through conduits of a relatively restricted size. Build up of condensation on the inside wall of the conduit is a potential result of this high humidity. The purpose of including a breathable region or regions in the conduit wall is to allow diffusion of water vapour from the expiratory limb of the breathing circuit along the path thereof. This can reduce the build up of condensation within the expiratory limb by drying the humidified gases during their flow through the expiratory limb. This furthermore reduces the humidity of the gases arriving at ancillary equipment, such as filters, ventilators and the like reducing the risk of condensation accumulation, thereby improving their operation.

The preferred breathable material is a hydrophilic polyester block copolymer formed into a homogeneous flat film. An example of such a film is sold under the brand SYMPATEX. This material has been found particularly suited to very thin film productions and therefore find particular suitability in the manufacturing method of the present invention.

The following embodiments will be described with particular reference to breathable thin film wall construction from materials such as SYMPATEX. It will be appreciated however, that in the following described embodiments the material used to form the conduit walls may be either breathable or non-breathable and may also include combinations of both breathable and non-breathable materials. It will be also appreciated for the following described embodiments that the film(s) supplied to the former(s) may be supplied either as a preformed tape wound on to a reel or may alternatively be supplied

directly to the former from an extruder. Each of these options have associated advantages and disadvantages which will be discussed later. It will also be appreciated by those skilled in the art that the materials supplied to the former may require guides and/or rollers in order to position the materials accurately and provide the necessary tension.

As a corollary of material cost it is preferred that the conduit wall be manufactured to have a relatively low wall thickness, so much so that the conduit wall membrane may be insufficiently sturdy to be self supporting. Spiral or helical reinforcing members are therefor provided as part of the tubular membrane to provide support. The helical or spiral supporting members are formed from polymer plastic materials and may be of the same material used in the wall of the conduit or any other compatible plastics material.

Referring to Figure 1, the lay-up arrangement of a flexible breathing conduit known in the art is shown.

Referring to Figure 2, a breathing circuit limb is shown with a thin film flexible wall. The thin film is arranged in a spiral or helix such that the edge portions of adjacent layers overlap and form the wall of a tube. Interposed the overlapping edges of adjacent winds of film is a bead of polymer material bonded with the overlapping portions of film sealing the joint between windings and forming a continuous tube. The seam is formed between the edge of a first layer of film and the edge of a second, adjacent layer of film which is laid over top of the polymer bead while the bead is molten. The overlapping layer of film because it is so thin, follows the contour of the bead very closely and results in a smooth inner conduit wall.

An example of forming apparatus suitable for manufacturing the breathing tube according to a first preferred embodiment of the present invention described in Figure 2 is shown in Figure 3. The apparatus includes a former 1 preferably of a known type including a plurality of rotating rods arranged around a central support rod. The rods extend from and are rotated by a gearbox within a machine stock 2. At least in the tube forming region the rotating rods follow a helical path. The pitch angle of the rods relative to the support rod controls the pitch angle of the tube being formed. An example of such

a machine is a spiral pipeline mandrel available from OLMAS SRL of Italy.

Tube being formed on the former is rotated and advanced in the direction of arrow 3 by the movement of the rotating rods. The advance speed of the former is selected relative to the rotational speed so that the pitch of the helical laying of the strip or tape on to the former 1 is a little less than the width of the strip so that adjacent turns narrowly overlap. A first extruder 4 supplies a tape 5 of thin film polymer materials with a preferred width of approximately 10 millimetres. The tape 5 deposits on the former 1 in a helical fashion by action of the former. The pitch of the helical disposition of tape 5 is slightly less than the width of tape 5 and results in an overlap of approximately 2.5 millimetres. The helical deposition of tape 5 forms the wall 6 of the conduit. An extruder 7 extrudes a bead 8 of polymer material. The molten bead 8 deposits between the overlapping portions of adjacent winds of tape 5 and is sufficiently heated to weld to the strips of tape 5. In the preferred embodiment of the present invention the dimensions of the molten bead 8 are approximately 2.5 millimetres wide and 1.5 millimetres high. The conduit formed according to this preferred embodiment has an approximate internal diameter of 19 millimetres. For breathable wall conduits the thickness of the breathable film must be thick enough so that the conduit does not become too flimsy but must also be thin enough so that the conduit wall is sufficiently breathable. It has been found that with SYMPATEX, a wall thicknesses between 15 and 35 microns fulfill these requirements. The most preferred wall thickness for breathable conduits according to the preferred embodiment is approximately 25 microns. A wall thickness of 25 microns has been found to provide a useful balance between breathability, flexibility and strength.

During the continuous manufacture of breathing conduits according to the method described above it has been found that overheating problems may occur when very thin film is used in the conduit walls. The mandrel temperature is raised by the continuing application of the molten bead resulting in the extremely thin film overheating and sticking to the mandrel, causing the quality of the conduit wall to suffer. In order to overcome this problem it has been found that a sacrificial layer, wound onto the mandrel in an overlapping helix pattern before the application of the breathable extruded tape is capable of overcoming this problem. In order to accomplish this task the sacrificial layer

of tape must not stick to the mandrel or to the inside of the conduit wall. It has been found that a material such as polypropylene is ideally suited for the sacrificial layer. The preferred thickness of the polypropylene sacrificial layer is between approximately 20 and 60 microns. Referring to Figure 3, a sacrificial layer 17 is wound from reel 16 onto the former before the breathable extruded tape 5. The heat from the applied molten bead welds the overlapping layers of sacrificial layer to each other, but does not result in any bonding between the sacrificial layer and the conduit wall. Alternatively a secondary thermal welding process may be employed to weld the overlapping layers of sacrificial tape. The sacrificial layer preforms many additional advantageous functions as described below:

1. The dummy layer protects the rollers on the mandrel from being fouled by molten plastic.
2. The sacrificial layer increases the stability of the process and may help prevent the SYMPATEX layers from slipping.
3. The sacrificial layer provides a protective barrier between sharp edges on the mandrel and the SYMPATEX film.
4. The sacrificial layer shields the thin film from the higher operating temperatures of the mandrel and reduces overheating of the film.

A polypropylene layer can be easily removed from the inner wall of the finished conduit product as it does not stick to the mandrel or the conduit. Additional means such as water cooling of the mandrel may also be provided to reduce overheating.

Applying the molten bead between the overlapping layers of tape instead of over the top of the overlapping layers, improves the weld quality as both layers of tape that are to be welded are in physical contact with the molten bead. When the prior art forming method shown in Figure 1 is employed to manufacture conduits from preformed films, achieving good welds has been found to be problematic. This is due to the molten bead being deposited on top of the outermost layer and the need for the weld to penetrate through two or more layers.

Referring to Figure 4 there is shown two potential problems which may result in

the production of conduits with an inferior wall smoothness. The quality of the surface finish for the inner surface of a breathing conduit is very important as rough inner surfaces may hinder gases flow and may cause more condensation to build up in the conduit. A protruding portion 33 may result if the underlapping layer of film is not completely bonded to the molten bead. This problem occurs when the underlapping portion of film is too wide. In Figure 4 small voids 9 are created between adjacent strips of tape where the film does not closely conform to the contour of the molten bead. This may occur if the material used is not sufficiently supple. For this reason a construction technique of the present invention is especially suited to conduits fabricated from very thin film. The thin film is very flexible and able to conform very closely to the shape of the raised rib of the applied molten bead 8 during fabrication. By lapping very closely on to the bead and wrapping around the bead, the very thin film maintains a smooth inner surface on the finished conduit product as shown in Figure 2. Also the molten bead tends to flow to fill any voids resulting in a smooth conduit wall.

It has been found that breathing conduits formed according to the first preferred embodiment described above are extremely light, flexible and provide good crush resistance. However conduits having very thin walls may have a reduced resistance to axial deformation. Due to the very thin tape used to form the walls of the conduit the resulting product may be prone to expansion and/or contraction along the axis of the conduit. In use axial forces arising from patient breathing are capable of producing axial extension/contraction along the length of the conduit. In order to improve the axial stiffness of such breathing conduits, a second preferred embodiment will now be described.

In a second preferred embodiment shown in Figure 5 a plurality of reinforcing threads 10 running the length of the wall and spaced around the perimeter of the tube are aligned parallel to one another and to the major axis of the conduit. The threads 10 are supported on the helical bead 11, with the threads spanning the spaces between turns of the helical bead. In this embodiment it is preferable to choose the reinforcing threads (material, gauge, type and number) such that the threads are sufficiently stiff to resist

buckling under the transiently reduced internal pressures that could be expected during patient breathing. Unrestrained or excessive buckling of the threads could result in unacceptable levels of conduit axial contraction and/or extension. The axial threads 10 may be spun or braided fibres or drawn or extruded mono filaments or other equivalent forms. Preferably, tensile reinforcement is provided by braided or spun fibres while compressive reinforcement is provided by drawn or extruded mono filaments.

A preferred method of forming the tube according to the embodiment of Figure 5 is described with reference to the apparatus shown in Figure 6. In particular in the machine of Figure 6 the tube 12 is formed by helically wrapping a preformed tape or strip of polymer 13 on to a rotating former 14. The strip 13 unrolls from reel 15. In an analogous manner to that described previously for the first preferred embodiment, a sacrificial layer of polypropylene 17, is wound in an overlapping helix onto former 14 from spool 16. The sacrificial layer 17, between the mandrel and the conduit being formed, allows the extremely thin film to be shielded from the higher operating temperature of the mandrel and stops overheating of the film.

Tube being formed on the former is rotated and advanced in the direction of arrow 3. The advance speed of the former is selected relative to the rotational speed so that the pitch of the helical laying of the strip or tape on to the former 14, is a little less than the width of the strip so that adjacent turns narrowly overlap. An extruder 18 extrudes a bead 19 of molten polymer material. The molten bead 19 deposits between the overlapping portions of adjacent winds of tape 13 and is sufficiently molten to weld to the strips of tape 13. The molten bead becomes the helical reinforcement for the finished conduit.

A freely rotatable thread laying head 20 is located over the former after the bead extruder 18. The rotating head 20 carries a plurality of spools 21 holding reinforcing thread. The head 20 is rotatable by an electric motor and drive belt 22 and 23 respectively. The head 20 is preferably rotated at a speed synchronized with the speed of effective rotation of the product 12. Advancement of tube along the former 14 draws thread 24 from the spools 21 to be laid as parallel threads 10 on the outside of the reinforcing bead 19. Another thread 25 is drawn from spool 26 and wound onto the former overtop of the longitudinal threads 10, laid by thread laying head 20. The thread 25 is laid on the former

in a helical pattern such that the thread lies between the helical bead of molten polymer extruded from extruder 18. The purpose of thread 25 is to provide a temporary means of securing the plurality of longitudinal threads in position in preparation for permanent fixing. A second extruder 27 extrudes a second bead of molten polymer material 28 and deposits it over top the plurality of reinforcing threads 10 and directly on top of the first reinforcing bead 19. The second bead of molten polymer sandwiches the plurality of longitudinal threads between itself and the first reinforcing rib formed by polymer bead 19. Thread 25 however, lies between these overlapping reinforcing beads and does not become permanently bonded to the conduit wall, allowing it to be removed and discarded.

This embodiment of the invention provides a breathing circuit limb reinforced against crushing by the helical bead and against longitudinal extension by the axial threads 10 as well as providing a breathing conduit having all the advantages of the first preferred embodiment. The spanning threads 10 also provide an additional advantage by reducing direct contact between the user/environment and the surface of the tube, therefore reducing the risk of punctures and damage. The threads effectively provide an additional barrier against potential damage around the conduit wall.

A further breathing circuit component to which the present invention can be applied is catheter mounts. A catheter mount connects between a patient interfacing component such as a mouth piece, nasal mask or endotracheal tube and the dual limbs of the breathing circuit. Connection with the dual limbs of the breathing circuit is generally via a wye connector. The extreme flexibility of very thin walled tubes manufactured according to the present invention makes them particularly useful in a catheter mount component.

It should be appreciated that with all of the forming methods described involving winding of a narrow tape or strip to create a tube, it would be possible to wind two or more tapes or strips simultaneously onto the former so that the turns created by each tape are interposed by turns of other tapes, edges overlapping and being bonded together by an interposed extruded helical rib. For example a pair of tapes may be laid as a double helix. This would require a multiplication in the number of forming stations associated with the wound on components of the tube or conduit. Further it is envisaged that for methods

where a preformed tape is supplied to a former, the tape may be provided as a laminate having a very thin film layer and a reinforcing layer bonded to it. Where the very thin film layer is a breathable layer then the reinforcing layer is also permeable to water vapour.

A further preferred embodiment of the present invention is envisaged where thin walled breathing conduits are manufactured in a similar manner as described above but, where the conduit wall also preferably contains at least one thin conductive wire. Preferably a pair of wires is included in order to provide a means for heating the conduit. Heated conduits may reduce the build up of condensation in the conduit and may also offer a means to maintaining the temperature of humidified gases flowing through the conduit. Heated conduits are most often used in only the inspiratory arm of a breathing circuit but can also be used in the expiratory arm. Heated wall conduits may also be components of coaxial (unilimb) circuits, or be used in single limb applications such as for CPAP therapy. In such breathing conduits where the inspiratory arm includes heater wires, the corresponding connectors at least one end of the conduit will include an electrical connection suitable for connection with the humidified gases source in order to supply electrical energy to the conduit heater wires. Referring to Figure 7, a breathing conduit is shown including a pair of heater wires 31, embedded in the helical reinforcing bead.

A first preferred method of forming a conduit according to this embodiment of the present invention including a pair of heater wires will now be described with reference to Figure 8. The method is similar to the method previously described and illustrated in Figure 3, but an additional stage is required to lay a pair of parallel wires in between the overlapping adjacent winds of film in the edge area of the film that will become the seam. A pair of wires 31 are supplied from two reels 29 and 30. The wires are laid on top of the first wind of film, towards the edge, after it is laid on the former but before the molten bead is applied. Figure 8 shows a pair of heater wires 31 in hidden detail under the molten bead 8. The molten bead 8 is then laid over the wires on top of the first layer of film before the following overlapping wind of film wraps around the former and completes the tube. The resulting conduit is shown in Figure 7 and is similar to the previous embodiment shown in Figure 2 but with an additional pair of heater wires embedded in

the helical reinforcing bead of the conduit wall. In this preferred embodiment, a sacrificial layer 17 may also be wound in an overlapping helix onto the former from spool 16. The sacrificial layer 17 may be a polypropylene layer or some other material that will not weld to the conduit wall. The sacrificial layer 17 between the mandrel and the conduit being formed, allows the extremely thin film to be shielded from the higher operating temperature of the mandrel and stops overheating of the film.

A further preferred method of forming a conduit according to the present invention including a pair of heater wires will now be described.

The above method of forming a conduit discloses an online process for winding a pair of heater wires into the conduit wall. It is envisaged that a pair of heater wires may be included in a preformed tape which would then be used to form the walls of the conduit in a similar method to that described above and illustrated in Figure 3. Figures 9a and 9b show cross sections of such a tape being formed by laying a pair of parallel wires a distance x from one edge of the tape. The length x of tape between the wires and the edge is then folded over and back onto the rest of the tape so as to enclose the pair of parallel wires, as shown by arrow 32. A secondary thermal welding process may then be employed to bond the folded portion of tape so as to permanently embed the parallel wires. It will be appreciated however that a secondary thermal welding process may not be necessary if the extruded tape is molten or partially molten when the folding occurs. In this case the two molten layers when folded and pressed together will bond.

Such a pre-formed tape including embedded wires may then be wound on to reels and supplied to a conduit forming process such as that described previously and illustrated in Figure 3 to produce a breathing conduit with a pair of integral heating wires. Figure 10 shows the lay-up of a breathing conduit formed by this embodiment of the present invention. The portion of thin film that wraps over the reinforcing bead and the adjacent wind on the former is only one layer thick and therefore is able to conform to the contour of the reinforcing bead. A tube formed accordingly to this preferred embodiment of the present invention therefore is able to retain all of the advantages of the previously described preferred embodiments, while having the additional advantage that a forming apparatus as described in Figure 3 may be employed to manufacture a conduit including

embedded heater wires without substantial modification to the forming apparatus. In such a case the extruder 4 is replaced with a reel of preformed tape such as that shown in Figure 9b and supplied to the forming apparatus.

DATED THIS 11th DAY OF September 2002
AJ PARK
PER *[Signature]*
AGENTS FOR THE APPLICANT

Prior Art



Figure 1



Figure 2

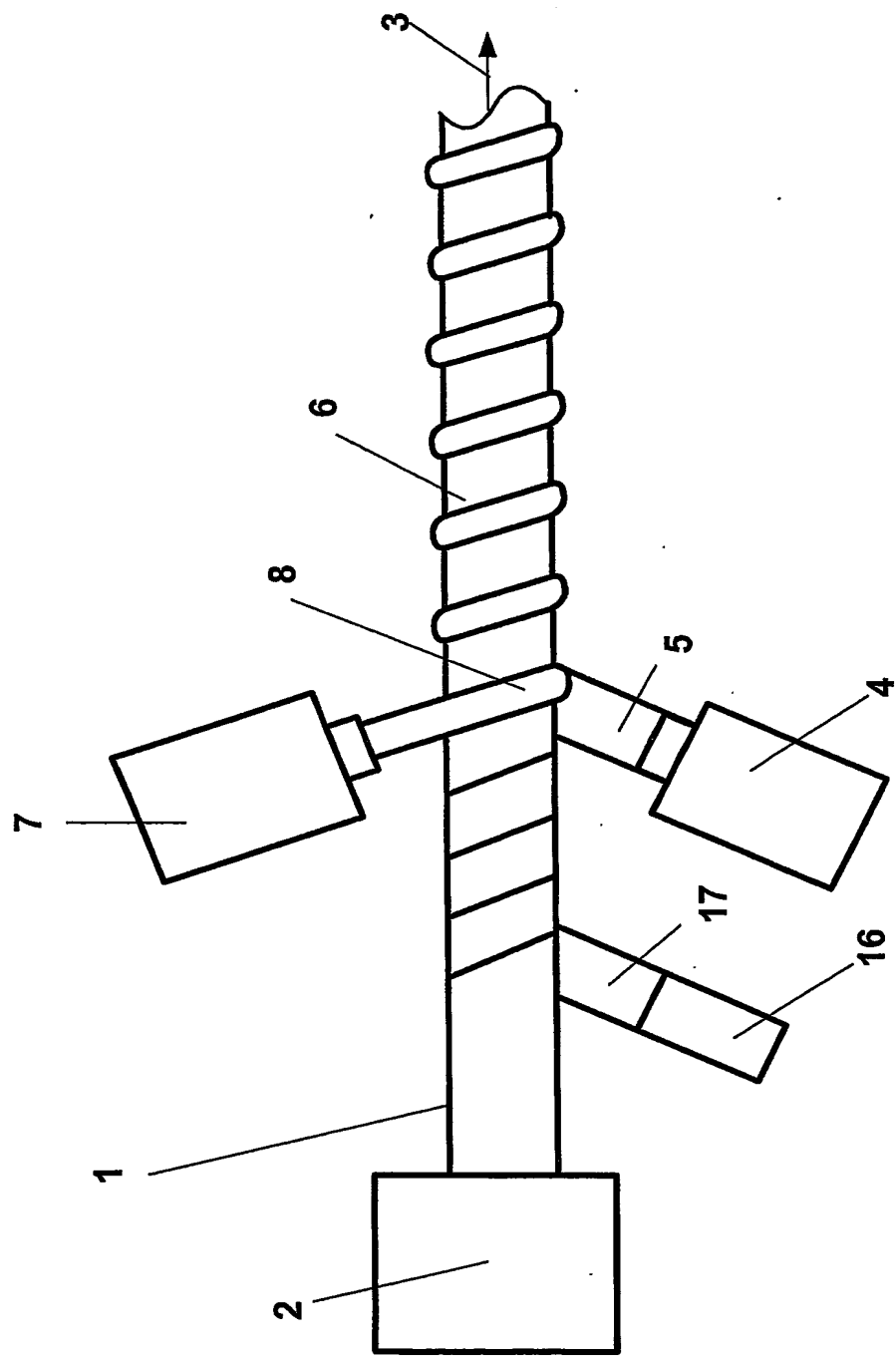


Figure 3

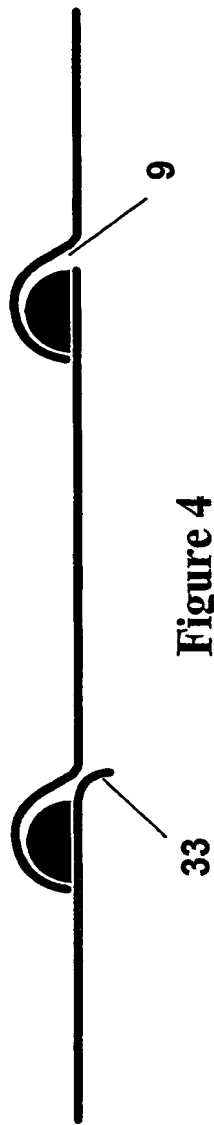


Figure 4

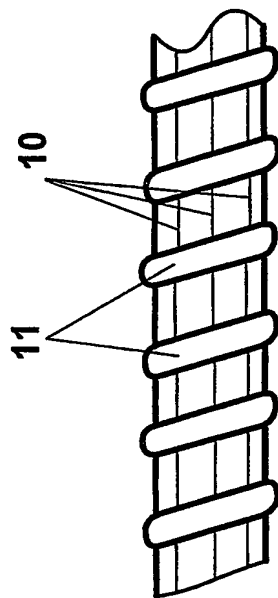


Figure 5

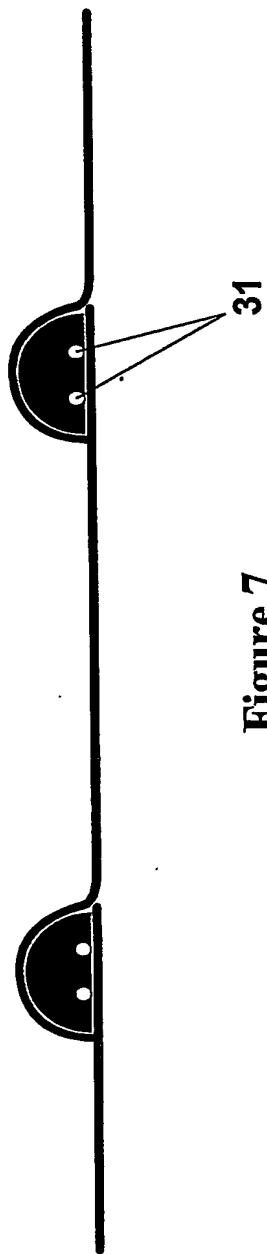


Figure 7

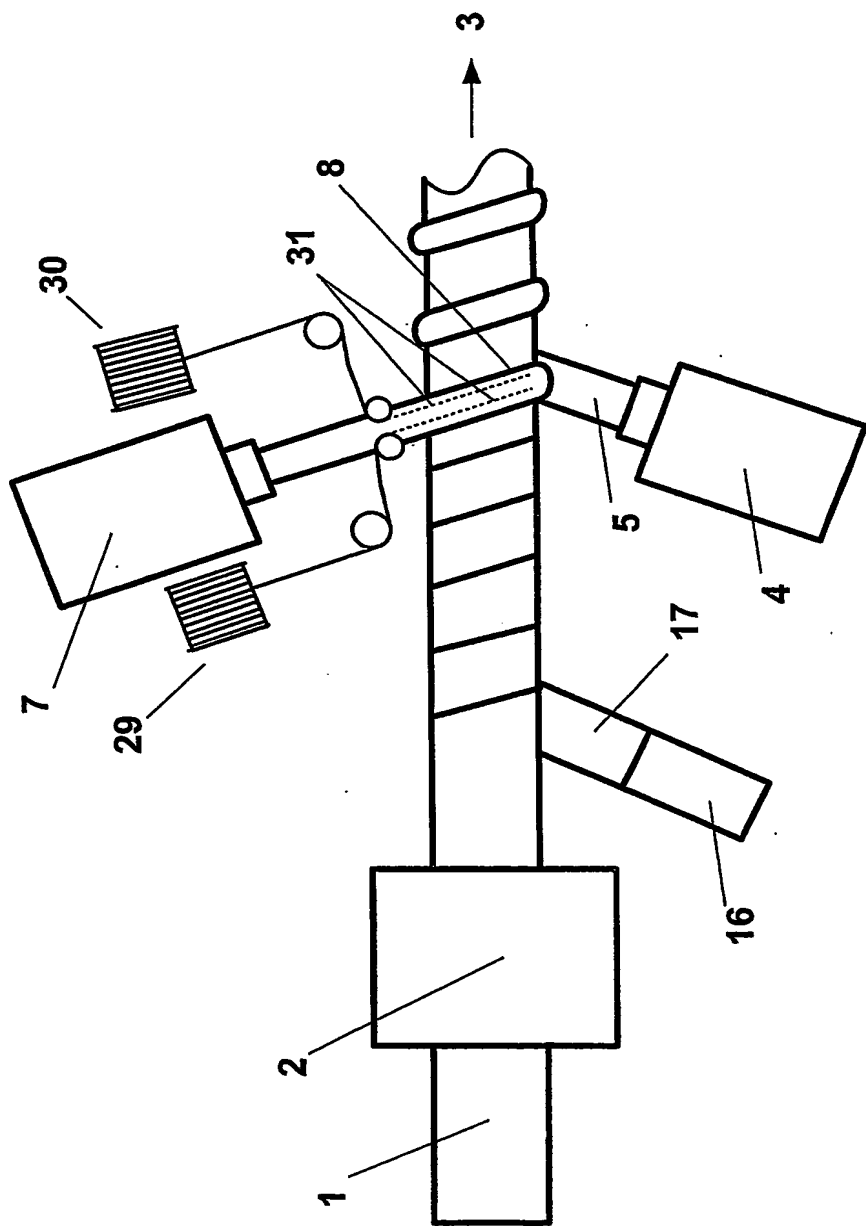


Figure 8

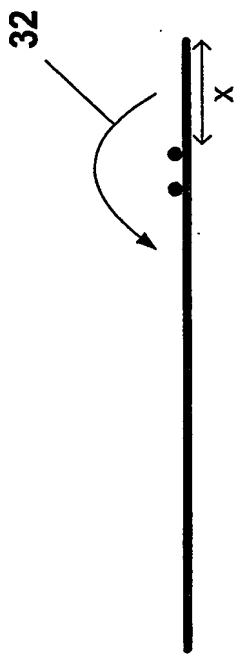


Figure 9 a



Figure 9 b



Figure 10